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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,651

03/31/2005

Maik Kindermann

2005-0427A

2263

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7590

05/08/2009

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,651	<b>Applicant(s)</b> KINDERMANN ET AL.	
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4-19,21-25 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 and 30 is/are allowed.
- 6) ☒ Claim(s) 2,4,5,8-19,21-25 and 31 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 5, 8-19, 21-25, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The “methotrexate moiety” language in claim 2 and 23 is unclear. Moiety formed how?

Unlike e.g. biotin, which has one standard way of binding, it is not clear how methotrexate will bind. Not including the amide N, there are four different O-or-N atoms which could have protons displaced.

2. The claim 2 provision for a plurality of labels is unclear. The formula shows only one L. If R4 can have several L groups attached, then the formula must be amended accordingly. Note in this regard that R4 is an alkylene group, which has exactly two bonds, one of which must be used to attached to R3. The traverse is unpersuasive. The amendment has made it clear that all L groups are to be attached to the R4, but that just exacerbates this problems. With L as a divalent group, it has only two bonds: one to R3, and one to a single L. If the L groups were attached to each other, this problem would not exist, but the claim language eliminates this possibility.
3. It is unclear where the list of labels in claim 2 ends. This is important because there can be a plurality of labels, but things that are not labels, there cannot be a plurality of these. Is “methotrexate moiety” a label, in which case there can be more than one, or is

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it a choice for L, in which case there is just one permitted, as the formula has just one L. The problem here is that the choice of "a bond..." is clearly not a label, therefore, the list of labels must have stopped by then. The remarks say "there can be no doubt" but do not actually say where the end of the labels list is. The examiner understands that it all belongs to the definition of L. The question is where the list of labels ends, because it is labels which can be plural. Anything which is L, but not a label, cannot be plural. The remarks about "structuring this definition in paragraphs" is not understood.

4. At next to last line of claim 2, what does "moiety with cell membrane-inserting properties" mean? Is this something which inserts a membrane into something, in which case, into what? Is it something which attaches itself to a membrane, i.e. inserts itself onto a membrane? Is it something which passes through? The traverse is unpersuasive. The traverse is unpersuasive. The remarks simply brush this off, saying one of ordinary skill in the art would know, but applicants appear to be unable to indicate just what it is that one of ordinary skill in the art would know.
5. R4, choice (b) is unclear. The material before "representing" would appear to cover both NHCO and CONH, but the claim goes on to give only the former. Is only the former intended? In addition, the "or more" would appear to permit NHNHCO as well as NHCONH, but again, these do not appear after the "represents". Are these included? The traverse is unpersuasive. The change is noted, but does not get at the problem. The new language says that only a single carbon is substituted by O, and it is adjacent to the N, but both NHNHCO as well as NHCONH meet that. Such groups may or may not be considered amides. The remarks do not address this point at all, as the remarks are silent on the issue.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/  
Primary Examiner  
Art Unit 1624

5/8/2009